MAY 2 3 2003

K030728

7601 Ganser Way
Madison, WI 53719
(608) 827-7111

510(K) SUMMARY
(As Required by 21 CFR 807.92(c))

A. Submitter's Name and Address

MPACS, LLC
7601 Ganser Way
Madison, WI 53719

Phone: (608) 827-7111
Fax: (608) 827-0162

B. Contact Person

Greg Sopotnick
Phone: (608) 827-7111
Fax: (608) 827-0162

C. Date of Submission: March 6, 2003

D. Device Name

D.1. Device Trade or Proprietary name: fyreLINK VL™

D.2. Device Common or Usual Name: Picture Archiving and Communications Systems (PACS)

D.3. Classifications: Image Processing System

D.4. Product Code: LLZ

D.5. Class: Class II

D.6. Classification Panel: Radiology

E. Equivalent Device

The equivalent legally marketed device is the Dyonics Vision 635 Digital Capture System (K011944) from Smith & Nephew, Inc., Endoscopy Division.

F. Device Description

fyreLINK VL (formerly echoLINK) now provides the endoscopy and surgical market a real-time solution for dealing with video data in a complete image management system. There are three major components that make up the fyreLINK VL product line; an image acquisition unit, a review station (either the fyreLINK station or a third party product), and a DVD library system or other archive device. The telemedicine system uses the same components except for the DVD library system. Appendix D shows an example of how an image acquisition unit can be arranged to provide a particular customer solution.

The fyreLINK VL Image Acquisition Unit (IAU) is the key component of the fyreLINK VL device. It uses a hardware video converter to convert analog video coming from a surgical video system to streaming digital video in real time. This streaming digital video is then compressed using MPEG 2 technology and stored on its local hard drive as a MPEG2 file. The IAU can store up to 1000 minutes of digital video data on its internal hard disk. The data is available for immediate review on the IAU, or can be exported to another application or another workstation or archive. Each acquired recording is an individual file. Exams can consist of a single continuous recording of the entire procedure, or a collection of shorter recordings of areas of interest. Still images may also be captured and saved as bitmap or JPEG files. The IAU is built on a Windows 2000 platform, and is network-ready for transferring patient data to a local or central archive system and/or to a physician's review station. The IAU's compact size allows it to be a direct replacement for existing VCR's used in endoscopic and microscopic surgical procedures. The IAU platform can consist of either a laptop or desktop type computer. The device has an electronic report generator that will allow the user to enter exam information as part of a paperless reporting system. The IAU, when configured as part of a WAN environment, can be a part of a remote access telemedicine system. The IAU is controlled by MPACS proprietary software.

fyreLINK VL offers two review station solutions. Acquired images can be reviewed at the IAU, or the image files can be exported for use with another application. THE REVIEW FUNCTION OF FYRELINK VL SOFTWARE LABELS ALL RECALLED IMAGES WITH THE TYPE OF COMPRESSION USED AND THE COMPRESSION RATIO.

fyreLINK VL used in a network environment can integrate with a mass archive solution already in place. As an alternative, the IAU includes a DVD recorder built in, to permit immediate local archival of endoscopic or microscopic surgical procedures.

MPACS can supply network solutions for integrating the fyreLINK VL components. In a network configuration, the image acquisition unit moves patient studies directly to a server. The networked review station is able to review both on-line and near-line studies. Network solutions can also include telecommunication links such as T1, DSL, and cable modem connections for telemedicine.

G. Intended Use

This device is intended for use when there is a need to convert endoscopic and microscopic surgical video to a digital video format for subsequent review and archiving. This device will also transfer the digital video over digital networks and/or digital communication lines.

H. Substantial Equivalency Comparison

fyreLINK VL and Dyonics Vision 635 Digital Capture System are technologically equivalent in their capture of video images. Both convert an analog video signal to digital data, and then use the MPEG compression standard to create a file for storage and playback. In addition, both devices are capable of exporting data files in DICOM format, and both devices also capture still images in bitmap and JPEG format.

Data files on both devices are initially stored to a large internal hard drive. Both devices also can export to a network storage device via an Ethernet connection.

I. Conclusions

fyreLINK VL's performance is the same as the equivalent marketed device. Both devices are required to acquire or digitize full-motion (30 frames per second) analog video in real time. Likewise, both devices can playback the stored digital video in real-time.

Based on the intended use and the comparisons between the fyreLINK VL device and the legally marketed device, there are all the indications that the fyreLINK VL device is substantially equivalent to the Dyonics Vision 635 Digital Capture System device.

(End of 510(k) Summary)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 23 2003

Mr. Greg Sopotnick
QA Manager
MPACS, LLC
7601 Ganser Way
MADISON WI 53719

Re: K030728
Trade/Device Name: fyreLINK VL
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: March 6, 2003
Received: March 7, 2003

Dear Mr. Sopotnick:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K030728

Device Name: fyreLINK_VL

Indications for Use:

This device is intended for use when there is a need to convert endoscopic and microscopic surgical video to a digital video format for subsequent review and archiving. This device will also transfer the digital video over digital networks and/or digital communication lines.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David R. Lepore

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030728

Prescription Use ✓

(Optional Format 3-10-98)

(Posted July 1, 1998)